

# Navajo Nation Human Research Review Board

## Meeting Agenda

Meeting Date: 2022-12-20 Meeting Time: 9:00 AM  
Location: Zoom

### MEMBERS:

Mrs. Beverly Becenti-Pigman - Community ☐  
Dr. David Begay, Ph.D. - Scientific Education ☐  
Mr. Delvin Yazzie, MPH - Epidemiology ☐  
Dr. Kalvin White, Ph.D. - Scientific Education ☐  
Dr. Nanibaa' Garrison, Ph.D. - Genetics, Bio-Ethics ☐  
Dr. Rebecca Izzo-Manymules, Ph.D. - Chairperson - Education ☐  
Dr. Sonya Shin, MD - Medicine ☐  
Ms. Ursula Knoki-Wilson, MSN, MPH - Nursing ☐

### OLD BUSINESS:

I. Meeting Called to Order:

II. Roll Call:

- Invocation:

- Introduction:

III. Review and Approval of Agenda:

IV. Review and Approval of July 19, 2022 Meeting Minutes:

### NEW BUSINESS:

V. Review and Acceptance of Quarterly Reports:

VI. New Presentations:

VII. Returning Presentations:

VIII. Noon Hour Discussion: 1) Navajo Nation Genetics Research Policy, 2) Revision of Navajo Nation Human Research Code.

IX. Serious Adverse Events (SAEs):

X. Review and Acceptance of Manuscripts: 1) Health care reliance among Navajo adults during the COVID-19 pandemic: a cross-sectional study NNR-20.391 Dr. Heidi Brown 2) Nirsevimab for Prevention of RSV Lower Respiratory Tract Disease in Term and Late Preterm Infants. NNR-19.357 Dr. Laura Hammitt; 3) Potential Effects of

Long-term Exposure to Air Pollution on Dementia:  
A Longitudinal Analysis in America Indians Aged  
55 years and Older, NNR-11.342, Dr. Joan  
O'Connell.

XI. Announcements / Adjournment:

## QUARTERLY REPORTS

1. NNR-02.106 PI: Dana Dabelea  
SEARCH for Diabetes in Youth Study  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering February 15, 2022 - May 15, 2022 period

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2. NNR-11.321 PI: Christine Samuel-Nakamura  
Uranium in the plant-animal-human food chain near abandoned mining sites and structures in an American Indian community in Northwestern New Mexico  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering August 21, 2022 - November 9, 2022 period

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3. NNR-19.358T PI: Sonya Shin  
Inter-generational Impact of Navajo Fruit and Vegetable Prescription (FVRx) Program  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering September 17, 2022- December 17, 2022 period

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4. NNR-19.367 PI: Craig Chaya  
Patterns of Blindness in the Navajo Nation: A Retrospective Study  
Reason on Agenda: Quarterly Review  
Description: Request View and Acceptance of Quarterly Report (with attachments) covering July 2022 - October 2022 period

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5. NNR-21.412 PI: Joel Gittelsohn  
Formative Research to Improve WIC Participation in Three Diverse Native American Communities  
Reason on Agenda: Quarterly Review  
Description: Request Review and Acceptance of Quarterly Report covering June 15, 2022 - September 15, 2022 period

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6. NNR-18.302 PI: Mark Bauer  
Navajo NARCH Partnership: Evaluation of the Student Enhancement Program  
Reason on Agenda: Manuscript  
Description: Request Acknowledgement and Acceptance of Published Manuscript Titled: Dine' (Navajo) Traditional Knowledge Holders' Perspective of COVID-19.

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## NEW PRESENTATION(S)

1. NNR-22.456 PI: Dornell Pete

Navajo ABID Study II: Helicobacter pylori risk and treatment experiences in Navajo Adults

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study. submission of NAIHS HIPPA Waiver Letter, Fred Hutch IRB Letter, Revised Protocol. (TABLED at 10-18-22, 11-15-22 Meetings) PI to obtain NAIHS HIPPA Waiver agreement, and Sponsor or University IRB Approval Letter.; Date Received - 10/10/2022

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2. NNR-22.458 PI: James McKenzie

Dine Language and Culture Revitalization-Focused Schools

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Submission; Date Received - 12/05/2022

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3. NNR-22.459 PI: Amos Winter

Co-Design of Community Desalination in the Navajo Nation

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 12/07/2022

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4. NNR-22.460 PI: Ashish Amresh

Project Lets Talk Code

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 12/07/2022

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5. NNR-22.461 PI: Jeffery Hovermill

Project co-STEM

Reason on Agenda: NEW

Description: Remarks: Request Review and Approval of New Study; Date Received - 12/08/2022

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#### RETURNING PRESENTATION(S)

1. NNR-18.330 PI: Laurie Hudson

Thinking Zinc

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering January 22, 2023 - January 21, 2021 period- attached revised consent form for signature.

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2. NNR-02.110 PI: Vallabh Shah

Diabetes Prevention Program Outcomes Study (DPPOS)

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendments: 1) Revised Protocol Version 5.0, 2) Revised Consent Form, 3) Remote Consent (Phone or Video), 4) Revised MRI and PET/CT Imaging.

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3. NNR-09.241 PI: Barbara Overman

Giving Voice to Health Values from within the Navajo Culture

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request Covering 1) August 1, 2021 - July 31, 2022, 2) August 1, 2022 - July 31, 2023 periods

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering 1) August 1, 2022 - October 3, 2022, 2) August 1, 2021 - October 31, 2021, 3) November 1, 2021 - January 21, 2022, 3) February 1, 2022 - April 30, 2022, 4) May 1, 2022 - July 1, 2022, 5) May 1, 2021 - July 31, 2021

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4. NNR-15.231 PI: Sara Selig

Engaging Patients and Stakeholders to Improve Cancer Outcomes in Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 15, 2022 - December 15, 2022 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering December 15, 2021 - December 15, 2022 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering December 15, 2022 - December 15, 2023 period

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5. NNR-17.287 PI: Hannah Sehn

Understanding the Structural Barriers and Opportunities to Improve Cancer Treatment on Navajo Nation

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 15, 2022 - December 15, 2022 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering December 15, 2021 - December 15 2022 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering December 15, 2022 - December 15, 2023 period

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6. NNR-16.263 PI: Robin Harris

Helicobacter Pylori Infection and Stomach Cancer

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports Covering 1) June 1, 2022 - August 31, 2022; 2) September 1, 2022 - November 30, 2022 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering November 29, 2021 - November 30, 2022 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request Covering November 30, 2022- November 30, 2023 period

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7. NNR-21.398 PI: Karletta Chief

Assessing Navajo COVID-19 Risks and Increasing Indigenous Resilience

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering: 1) March 17, 2021 - June 17, 2021; 2) June 17, 2021 - September 17, 2021; 3) September 17, 2021 - December 17, 2021; 4) December 17, 2021 - March 17, 2022; 5) March 17, 2022 - June 17, 2022; 6) June 17, 2022 - September 17, 2022; 7) September 17, 2022 - December 17, 2022 periods

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering March 17, 2021 - March 17, 2022 period

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Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering March 17, 2022 - March 17, 2023 period

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8. NNR-20.391 PI: Heidi Brown

Impact of the COVID-19 Pandemic on Navajo Adults and Health Care Providers

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering March 2021 - March 2022 period

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9. NNR-20.373T PI: Vincent Werito

Cultural Characteristics of Successful Aging from a Dine Perspective: The Significance of Dine Elder knowledge in Achieving Long-Life Happiness as community well-being

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 12, 2022 - December 12, 2022 period

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Reason on Agenda: (Other)

Description: Request Acceptance and Acknowledgement Letter of Acceptance of Abstract for Conference Presentation.

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10. NNR-21.428 PI: Vincent Werito

Wide Engagement for Assessing Vaccine Equity in New Mexico (WEAVE NM)

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval of Continuation Request covering November 16, 2022 - November 16, 2023 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering November 16, 2021 - November 16, 2022 period

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering September 12, 2022 - December 12, 2022 period

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11. NNR-14.192 PI: Hendrik deHeer

Physical activity and cancer among Native American cancer survivors: A pilot study.

Reason on Agenda: Continuation Request

Description: Request Acceptance and Approval Continuation Request covering December 20, 2022 - December 19, 2023 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval Annual Report covering December 17, 2021 - December 19, 2022 period

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Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Reports covering 1) December 17, 2021 - March 14, 2022, 2) March 15, 2022 - June 20, 2022, 3) June 21, 2022 - September 19, 2022 periods

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12. NNR-15.212 PI: Mark Solomon

2015 Safety Belt Use Estimates for the Indian Nations.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering October 1 - December 31, 2022 period

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Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual Report covering July 2021 - July 2022 period

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13. NNR-19.349 PI: Tasha Seneca Keyes

Restorative Justice practices for improving school-based relationships

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Abstract Conference Presentation on January 11-15, 2023 in Phoenix, AZ at 27th Annual Conference of the Society for Social Work and Research (SSWR)

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Reason on Agenda: Revised Protocol

Description: Request Acceptance and Approval to Revised PI and Protocol University of Utah to California University San Marcos.

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Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of the Dissemination Plan for Community Stakeholders.

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14. NNR-21.409 PI: Carmen George

Expanding and Evaluating a community-based intervention to increase healthy beverage consumption by Navajo Preschool Children

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering July 20, 2022 - October 20, 2022 period

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Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to 1) to revise Caregiver Survey to add additional questions; 2) revise Focus Group Interview Guide to add additional questions

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Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Approval on 1) Research Brief, 2) Pamphlet, 3) Final Convening Powerpoint.,

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15. NNR-15.199 PI: Carmen George

REACH for Healthy Navajo Communities.

Reason on Agenda: Quarterly Review

Description: Request Review and Acceptance of Quarterly Report covering June 17, 2022 - September 17, 2022 period

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Reason on Agenda: Approval for Dissemination

Description: Request Acceptance and Approval of Dissemination Materials: Establishing Certification for Community Health Workers on the Navajo Nation, 2) Community Partnerships for Trail Enhancement on Navajo Nation

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16. NNR-21.423 PI: Akash Gupta

Evaluating the Impact of the Gallup COVID-19 Respiratory Shelter

Reason on Agenda: Annual Report

Description: Request Acceptance and Approval of Annual and Final Report covering October 27, 2021 - October 27, 2022



period

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17. NNR-22.442 PI: Nanette Lopez

A culturally-Relevant Micronutrient-Dense Plant Rich (mNDPR) dietary intervention for Native American  
Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to add new research materials to protocol.

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18. NNR-19.357 PI: Laura Hammitt

A Phase 3 Randomized, Double, Placebo-controlled Study to evaluate the Safety and Efficacy of MEDI 8897, a Monoclonal Antibody with an Extended Half-Life Against respiratory Syncytial Virus, in Healthy Late Preterm and Term Infants (MELODY)

Reason on Agenda: (Other)

Description: Request Review and Acknowledgement of Investigator's Brochure edition 6.0 May 27, 2022

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19. NNR-22.445 PI: Joshuaa Allison-Burbank

Piloting + Connection is Medicine

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment of Research Plan and Suicide Risk Safety Procedures.

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20. NNR-21.419 PI: Joshuaa Allison-Burbank

Project Safe Schools: Re-opening schools serving Native children and adolescents SAFELY

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to revise the Research Plan and Suicide Risk Safety Procedures.

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21. NNR-22.457 PI: Joshuaa Allison-Burbank

Language is Medicine: A Language Nutrition Intervention to Prevent Development Delay in Dine Children

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to Reld-Referral form to indicate the recruitment area within 50 Miles of JHCH Shiprock Office, not Northern Navajo Medical Center, and with updated Center's new logo.

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22. NNR-22.449 PI: Ashley Lee

Dine' Household Water Survey

Reason on Agenda: Amendment

Description: Request Acceptance and Approval of Amendment to modified research plan, revise the household water questionnaire and new recruitment note.

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23. NNR-11.342 PI: Joan O'Connell

Comparative Effectiveness of Healthcare Delivery Systems for American Indian and Alaska Native using Enhanced Data Infrastructure

Reason on Agenda: Conference Presentation

Description: Request Acceptance and Approval of Three Abstracts for a conference in January 2023 at the Alzheimer's Association International Conference. Abstracts Titled: 1- Effects of Depression and Diabetes on Dementia Risk among American Indian and Alaska Native People, 2- Gender and Age Difference in the Association between Depression and Dementia among American Indian and Alaska Native People, 3- Dementia Prediction Model for American Indian and Alaska Native People based on Electronic Health Record Data Using Machine Learning Algorithms.

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#### SERIOUS ADVERSE EVENT

1. NNR-20.374 PI: Laura Hammitt

Immunogenicity of H, Influenzae type b PRP-OMP vaccines in American Indian and Alaska Native Children (the HibVax Study)

Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: Viral URI

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Reason on Agenda: Primary - Off Site SAE

Description:

Diagnosis: COVID

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*Last Page and End of Agenda*